

MOXIVET 150MG/ML INJECTION

Description and Composition

MOXIVET 150MG/ML INJECTION is an off-white to grayish yellow oily suspension. Each ml contains 150mg of Amoxicillin (as trihydrate) as its active ingredient and 1mg Chlorocresol as its preservative.

Pharmacodynamics

Amoxicillin is a broad-spectrum antibiotic of the beta-lactam family that belongs to the aminopenicillin group. This substance has a time-dependent bactericidal activity and acts against gram-positive and some gram-negative microorganisms. The antibacterial action of amoxicillin is based on a mechanism that prevents the biochemical processes of bacterial wall synthesis via irreversible and selective inhibition of different enzymes involved in these processes, mainly transpeptidases, endopeptidases and carboxypeptidases. In susceptible species, the inadequate synthesis of the bacterial wall leads to an osmotic imbalance which particularly affects the growth of bacteria (when the processes of synthesis of the bacterial wall are particularly important), ultimately inducing the lysis of the bacterium.

Species considered sensitive to amoxicillin include Gram-positive *Streptococcus* spp., Gram-negative *Pasteurellaceae* and *Enterobacteriaceae*, including *E. coli* strains. Bacteria normally resistant to amoxicillin are staphylococci that produce penicillinase, some *Enterobacteriaceae* such as *Klebsiella* spp., *Enterobacter* spp., *Proteus* spp. and other Gram-negative bacteria such as *Pseudomonas aeruginosa*.

There are three main mechanisms of beta-lactam resistance: beta-lactamase production, impaired expression or modification of penicillin binding proteins (PLPs), and decreased penetration of the outer membrane. One of the most important is the inactivation of penicillin by the beta-lactamase enzymes produced by certain bacteria. These enzymes are able to cleave the beta-lactam ring of penicillins, thus rendering them inactive. Beta-lactamase could be encoded in chromosomal or plasmidic genes. Acquired resistances are common in gram-negative bacteria such as *E. coli* that produce different types of beta-lactamases that remain in the periplasmic space. Cross-resistance is observed between amoxicillin and other penicillins, particularly aminopenicillins. The use of broad-spectrum beta-lactam drugs (such as aminopenicillins) can induce selection of multidrug-resistant bacterial phenotypes (eg, those producing broad-spectrum beta-lactamases [ESBL]).

Pharmacokinetics

Amoxicillin is mainly distributed to the extracellular compartment. Its distribution in tissues is facilitated by the fact that it binds little to plasma proteins. The concentrations in lung, pleural and bronchial tissues are identical to those found in plasma. Amoxicillin diffuses into pleural and synovial fluid as well as into lymphoid tissues. A small proportion of amoxicillin (about 20%) is biotransformed in the liver by hydrolysis of the β -lactam ring, producing inactive penicilloic acid. Amoxicillin is mainly excreted in the active form by the kidneys, then by the bile duct and through the milk.

Indication

In cattle, sheep, swine, dogs and cats:

Treatment of digestive, respiratory, urogenital, cutaneous and soft tissue infections caused by bacteria sensitive to amoxicillin.

Recommended Dose

Cattle, sheep and pigs: Intramuscularly only.

Dogs and cats: Subcutaneously or Intramuscularly.

Shake the bottle vigorously for complete resuspension before use. To ensure correct dosing, the weight of the animal should be determined as accurately as possible to avoid underdosing. The recommended dosage is 15mg per kg body weight, equivalent to 1ml per 10kg, to be repeated once after 48 hours. The maximum injection volume per site is 20ml. A separate injection site should be used at each administration.

Route of Administration

To be given only by intramuscular injection to cattle, sheep and swine.
To be given by intramuscular and subcutaneous injection in dogs and cats.
Shake the bottle vigorously for complete resuspension before use.

Contraindication

Do not administer intravenously or intrathecally.
Do not administer to rabbits, hamsters, gerbils or guinea pigs.
Do not use in case of hypersensitivity to penicillins, cephalosporins or any of the excipients.

Warning and Precautions**Special warnings for each target species:**

This product is not effective against beta-lactamase producing organisms. Total cross-resistance has been observed between amoxicillin and other penicillins, particularly aminopenicillins. If antimicrobial susceptibility testing shows resistance to penicillins, the use of this product/amoxicillin should be carefully evaluated, as its effectiveness may be reduced.

Special precautions for use:**Special precautions for use in animals:**

The use of the product should be based on the results of a susceptibility test of bacteria isolated from the animal. If this is not possible, treatment should be based on local epidemiological data (region-wide and farm-level) on susceptibility of the target bacteria.

Official, national and regional regulations for antibiotic therapy should be taken into account when using the product. Use of the drug other than the recommendations may increase the prevalence of amoxicillin-resistant bacteria and reduce the effectiveness of treatment with other penicillins due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Handle with care to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately. Penicillins and cephalosporins can induce hypersensitivity (allergy) after injection, inhalation, ingestion or skin contact. This hypersensitivity to penicillins can lead to cross reactions with cephalosporins and vice versa. Allergic reactions to these substances can sometimes be serious.

- a) Do not handle this product if you have known sensitivity, or if you have been advised not to handle this type of preparation.
- b) Handle this product with care to avoid exposure, and take all precautions.
- c) If after exposure to the product you experience symptoms such as a rash, you should consult a doctor and show him this warning. Swelling of the face, lips and eyes or breathing difficulties are more serious symptoms that require urgent medical advice.
- d) Wash hands after use.

Other Precautions:

None

Interaction with Other Medicaments

In general, it is inadvisable to use bactericidal and bacteriostatic antibiotics simultaneously. Beta-lactams are known to interact with bacteriostatic antibiotics such as chloramphenicol, macrolides, sulfonamides and tetracyclines. Penicillins also act synergistically with aminoglycosides.

Pregnancy and Lactation

Can be used during pregnancy and lactation.

Side Effects

In very rare cases, allergic reactions, ranging in severity from mild skin reaction, such as urticaria, to anaphylactic shock, may occur. In case of allergic reaction, treatment should be discontinued and symptomatic treatment instituted.

In rare cases, local irritation may occur due to amoxicillin injection. The frequency of this adverse reaction can be reduced by decreasing the injected volume per site of administration. Irritation is generally of low intensity and subsides spontaneously and rapidly. The frequency of adverse events is defined as follows:

- very common (adverse effects in more than 1 animal in 10 treated animals)
- frequent (between 1 and 10 animals out of 100 treated animals)
- uncommon (between 1 and 10 animals per 1000 treated animals)
- rare (between 1 and 10 animals out of 10,000 treated animals)
- very rare (less than one in 10,000 animals treated, including isolated cases).

Symptoms and Treatment of Overdose

The safety profile of amoxicillin is characteristic of that of other penicillins, its intrinsic toxicity being very low. Amoxicillin has a wide margin of safety. Treatment in case of overdose is symptomatic.

Storage Condition

Store below 30°C.

Shelf life

3 years. Following withdrawal of the first dose, use the product within 24 hours. Any unused material should be discarded.

Withdrawal Periods

Cattle:

- Meat and offal: 28 days.
- Milk: 84 hours.

Pigs:

- Meat and offal: 19 days.

Sheep:


- Meat and offal: 19 days.

Do not use in sheep producing milk for human consumption.

Packing

20ml, 50ml, 100ml.

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